IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

KAREN ROWLAND, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01474 Judge Mark R. Hornak

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GEORGE MACHEN and STACY MACHEN, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01476 Judge Mark R. Hornak

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MICHELLE PRATT ORR, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01715 Judge Mark R. Hornak

OPINION

Mark R. Hornak, United States District Judge

Plaintiffs Karen Rowland ("Ms. Rowland"), George Machen ("Mr. Machen"), Stacy Machen ("Mrs. Machen"), and Michelle Pratt Orr ("Mrs. Orr") bring strict liability, negligence, and breach of warranty claims against the Defendant, Novartis Pharmaceuticals Corporation ("NPC"), alleging that they or their spouse developed a painful and permanently disfiguring condition as a result of using NPC's prescription medication for the purpose of managing metastatic bone cancer. Pending before the Court is a deluge of *Daubert* motions filed by NPC to exclude opinion testimony from Plaintiffs' retained experts and to exclude causation testimony from Plaintiffs' case-specific retained and non-retained experts (their "treating physicians") under Federal Rule of Evidence 702 ("Rule 702"). Mrs. Orr has also filed a pending *Daubert* motion to exclude certain expert testimony from two of NPC's case-specific experts. The Court has carefully considered all of the parties' voluminous motions, briefs in support, responses, and reply briefs. It has the benefit of a multitude of rulings from its sister federal and state courts on virtually identical motions. All counsel are well-familiar with them. The Court has no independent reason to reinvent the wheel as to commonly raised, litigated, and decided issues in those regards, except as specifically stated herein. In attempting to avoid comparisons to Tolstoy[1], the Court will now seek to rule succinctly on each of these motions.

I. BACKGROUND AND FACTS

The Court assumes the parties' familiarity with the factual background and wending procedural history of this case but will provide a brief review. These lawsuits involve Zometa, a Food and Drug Administration ("FDA") approved intravenous bisphosphonate ("IV BP") prescription drug designed, manufactured, marketed, distributed, and sold by NPC for patients with cancer that has metastasized to their bones. Rowland Compl. ¶ 6 ("RC"). Ms. Rowland

[1] The proverbial "this is not *War and Peace*."

received Zometa in conjunction with her treatment for metastatic breast cancer, Mr. Machen was prescribed Zometa in relation to his metastatic Stage IV-B Hodgkin's disease, and John Orr ("Mr. Orr"), Mrs. Orr's late husband[2], received it relative to his treatment for metastatic Stage II multiple myeloma. *Rowland v. Novartis Pharm. Corp.*, 2013 WL 6145119, at *1 (W.D. Pa. Nov. 22, 2013) (ECF No. 107 at 2-3). Plaintiffs allege that they developed osteonecrosis of the jaw ("ONJ"), a permanently disfiguring and painful condition that may result in complete loss of the jaw bone. RC ¶ 1. More specifically, they claim they developed a form of ONJ caused by IV BPs, interchangeably referred to by the parties as bisphosphonate-related ONJ ("BRONJ"), bisphosphonate-induced ONJ ("BIONJ"), or bisphosphonate ONJ ("BONJ")[3], as a result of their Zometa use. *Id.* They bring claims for strict products liability, negligence, and breach of express and implied warranty against NPC on the basis that it failed to adequately warn of the risks associated with Zometa.

Ms. Rowland and the Machens originally filed suit in federal court in the District of Columbia. *See* RC, at 1 and Machen Compl. ("MC"), at ¶ 1. Mr. Orr initially filed suit in federal court in the Southern District of New York. *See* Orr Compl. ("OC"), at ¶ 1. All three cases were conditionally transferred to the Middle District of Tennessee ("the MDL court") for coordinated pretrial proceedings pursuant to the Multi-District Litigation Act, 28 U.S.C. § 1407. ECF No. 4. Along with the summary judgment motions it filed in the MDL court, NPC filed *Daubert* motions to exclude, for purposes of summary judgment, the expert testimony of Dr. Keith Skubitz ("Dr. Skubitz"), Dr. James Vogel ("Dr. Vogel"), Prof. Wayne Ray ("Prof. Ray"),

[2] Mrs. Orr entered this action as a party upon the death of Mr. Orr. ECF No. 47 at 2.

[3] In the interest of clarity, the Court will consistently refer to this condition as BRONJ. Where causation or incidence rate is concerned, since part of the dispute between the parties is whether Plaintiffs' IV BP use was the cause-in-fact of their injuries, the Court will refer to the more general condition of ONJ.

Dr. Robert Marx ("Dr. Marx"), Dr. Suzanne Parisian ("Dr. Parisian"), and Dr. Robert Fletcher ("Dr. Fletcher")[4], among others. The MDL court either denied or denied in part and mooted in part NPC's *Daubert* motions to exclude the expert testimony of Dr. Skubitz, Dr. Vogel, and Dr. Marx. ECF Nos. 73-4, 75-2, and 81-2. The MDL court also mooted NPC's motions to exclude the expert testimony of Prof. Ray and Dr. Parisian. ECF Nos. 77-2, 79-2. The MDL court then remanded these cases to this Court. ECF No. 9. The Court granted the parties' request to file *Daubert* motions on issues not decided by the MDL court. Those motions[5], as well as several that were filed with but not decided by the MDL court[6], are the subject of this decision.

[4] The parties have represented to the Court that Dr. Fletcher will not be called to testify at trial in these cases. Therefore, any *Daubert* motions related to his testimony will be denied as moot.

[5] The motions as to new *Daubert* issues are:

1) Defendant's Motion to Exclude Causation Testimony of Plaintiffs' Case-Specific Retained and Non-Retained Experts in the *Orr* Case (ECF No. 69);
2) Defendant's Motion to Exclude Causation Testimony of Plaintiffs' Case-Specific Retained and Non-Retained Experts in the *Rowland* Case (ECF No. 70);
3) Defendant's Motion to Exclude Causation Testimony of Plaintiffs' Case-Specific Retained and Non-Retained Experts in the *Machen* Case (ECF No. 71);
4) Defendant's Motion to Exclude Testimony of Dr. Robert Marx (ECF No. 72);
5) Defendant's Motion to Exclude Testimony of Dr. James Vogel (ECF No. 74);
6) Defendant's Motion to Exclude Testimony of Dr. Suzanne Parisian (ECF No. 76);
7) Defendant's Motion to Exclude Testimony of Prof. Wayne Ray (ECF No. 78); and
8) Defendant's Motion to Exclude Testimony of Dr. Keith Skubitz (ECF No. 80).

[6] The motions from the MDL court that remain pending are:

1) Defendant's Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses in the *Orr* Case (2:12-cv-01715-MRH, ECF No. 8-14, originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 26);
2) Defendant's Motion to Exclude Testimony of Plaintiff's Experts Dr. Suzanne Parisian, Dr. Robert Marx, Dr. Robert Fletcher, Prof. Wayne Ray, Dr. Keith Skubitz, and Dr. James Vogel (2:12-cv-01715-MRH, ECF No. 8-16, originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 28); and
3) Plaintiff Orr's Motion to Exclude Certain Testimony of Defendant's Case-Specific Experts, 2:12-cv-01715-MRH, ECF No. 8-12 (originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 20).

II. LEGAL STANDARD

Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 reflects "a liberal policy of admissibility." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). The Court acts as a gatekeeper and must screen purportedly scientific evidence to ensure that any and all such proffered evidence is both relevant and reliable. *Daubert v. Merrell Dow. Pharm.*, 509 U.S. 579, 589, 597 (1993). In determining the admissibility of expert testimony, courts have categorized the Rule 702 requirements as (1) the expert's qualifications, (2) the reliability of the expert's methods, and (3) the "fit" of the expert's methods to the facts of the case (i.e., whether the expert's methods are helpful to the fact finder). *See Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)).

Qualification "refers to the requirement that the witness possess specialized expertise." *Schnieder*, 320 F.3d at 404. "A broad range of knowledge, skills, and training qualify an expert." *Paoli*, 35 F.3d at 741. An expert's opinion is reliable if it has "good grounds" in scientific methods and procedures and is not based on "subjective belief or unsupported speculation." *Id.* at 742. The reliability inquiry is flexible and focuses "on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 594-95. Finally, an expert's testimony "fits" the issues in the case when it provides "a valid scientific connection to the pertinent inquiry." *Id.* at 591-92.

III. DISCUSSION

A. Dr. Robert Marx

Dr. Marx is a board certified oral and maxillofacial surgeon and a Professor of Surgery and Chief of the Division of Oral and Maxillofacial Surgery at the University of Miami Miller School of Medicine. ECF No. 73-2 at 2. Among his many qualifications listed in the record, *see id.*, 2-93, Dr. Marx is well-known for helping to recognize BRONJ and notify NPC of its existence and for co-authoring the medical literature that first identified and described BRONJ. *Id.* NPC seeks to exclude Dr. Marx's opinions as to four issues: (1) whether certain patients in the Aredia/Zometa[7] clinical trials had BRONJ; (2) general ONJ causation based on adverse event reports that Dr. Marx did not review; (3) the biological mechanism by which IV BP drugs allegedly cause ONJ; and (4) whether pre-Zometa dental treatment measures reduce the risk of BRONJ.[8]

1. Occurrence of BRONJ in Clinical Trials

With the exception of one case[9], federal district courts that have ruled on *Daubert* motions in this Multi-District Litigation ("Zometa courts") have consistently allowed Dr. Marx to opine that several patients in the Aredia/Zometa clinical trials likely had BRONJ.[10] Additionally, the MDL court held such testimony from Dr. Marx to be admissible. ECF No. 73-4. Under the law of the case doctrine, a transferee court such as this one is prohibited from

[7] Aredia is an IV BP predecessor to Zometa that is also manufactured by NPC.

[8] The parties have agreed that Dr. Marx will not testify regarding the state of mind, intent, or motives of NPC or the FDA, or of any current or former employees of either, or as to his criticisms of the Aredia/Zometa clinical trials. ECF No. 73 at 5 n.7.

[9] *Earp v. Novartis Pharm. Corp.*, 2013 WL 4854488 (E.D.N.C. Sept. 11, 2013).

[10] *See Deutsch*, 768 F. Supp. 2d at 448-49; *Davids*, 857 F. Supp. 2d at 276; *Hogan v. Novartis Pharm. Corp.*, 2011 WL 1533467, at *5 (E.D.N.Y. Apr. 24, 2011); *Guenther*, 2013 WL 1277928 at *2; *Georges*, 2012 WL 9064768 at *16-17; *Stambolian*, 2013 WL 6345566 at *11-12; *Brown v. Novartis Pharm. Corp.*, 2012 WL 9082913, at *13 (E.D.N.C. Jan, 9, 2012); *Winter*, 2012 WL 827305, at *7-8 (W.D. Mo. Mar. 8, 2012); *Hill*, 2012 WL 5451816 at *2; *Mathews*, 2013 WL 5780415 at *30-31.

vacating the order of the MDL court except in extraordinary circumstances that are not present here. *In re Pharmacy Benefit Mgrs. Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009). The Court concurs with the rulings of the Zometa courts and recognizes the MDL court's prior ruling in concluding that NPC's concerns as to the strength and accuracy of Dr. Marx's conclusions may be properly addressed on cross-examination.

2. General Causation Opinion Based on Adverse Event Reports

All Zometa courts that have ruled on Dr. Marx's general causation testimony – based on adverse event reports submitted to the FDA or NPC about patients who allegedly developed ONJ after being treated with Zometa – have held his opinion admissible.[11] The MDL Court also ruled that Dr. Marx's opinion on that issue was admissible, a fact mentioned in many of the other Zometa court rulings on this topic. ECF No. 73-4. This Court concurs in those conclusions and will deny NPC's *Daubert* motion as to Dr. Marx's general causation opinion.

3. Biological Mechanism Opinion

Zometa courts are similarly harmonious in their rulings on Dr. Marx's opinion regarding the biological mechanism by which IV BPs allegedly cause ONJ.[12] Pursuant to the reasoning of those courts, and due to Dr. Marx's authoritative experience and research in treating and studying patients with ONJ, the Court concludes that his testimony on this issue conforms to Rule 702.

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[11] *See Deutsch*, 768 F. Supp. 2d at 450-51; *Davids*, 857 F. Supp. 2d at 276; *Georges*, 2012 WL 9064768 at *17; *Stambolian*, 2013 WL 6345566 at *13; *Earp*, 2013 WL 4854488 at *3; *Brown*, 2012 WL 9082913 at *14-15; *Winter*, 2012 WL 827305 at *6; *Mathews*, 2013 WL 5780415 at *31.

[12] *See Deutsch*, 768 F. Supp. 2d at 438-39; *Davids*, 857 F. Supp. 2d at 276; *Jenkins*, 2012 WL 6213494 at *6; *Georges*, 2012 WL 9064768 at *18; *Stambolian*, 2013 WL 6345566 at *12-13; *Earp*, 2013 WL 4854488 at *3; *Brown*, 2012 WL 9082913 at 15-16; *Winter*, 2012 WL 827305 at *6-7; *Hill*, 2012 WL 5451816 at *2; *Mathews*, 2013 WL 5780415 at *31.

4. Pre-Zometa Dental Treatment Measures

Zometa courts appear to be unanimous in concluding that Dr. Marx's expert opinion as to the efficacy of pre-Zometa dental screenings in preventing BRONJ is qualified and reliable.[13] Additionally, in its *Daubert* order as to Dr. Marx, the MDL court concluded that his opinion on "treatment and preventative measures for ONJ" was admissible. ECF No. 73-4.

NPC now argues beyond *Daubert* that Dr. Marx's opinion is irrelevant to these cases under Federal Rules of Evidence 401-403. It asserts that Ms. Rowland actually was advised by her oncologist to receive a dental examination before beginning Zometa treatment but failed to do so, that Mrs. Orr has submitted no dental records predating the start of Mr. Orr's IV BP treatment, and that Mr. Machen's alleged BRONJ was not caused by a dental procedure but occurred spontaneously. "The theoretical reason for the pretreatment dental examination is to enable an individual to have invasive dental procedures performed *before* starting bisphosphonates that might cause ONJ." *Stambolian v. Novartis Pharm. Co.*, 2013 WL 6345566, at *14 (C.D. Cal. Dec. 6, 2013) (emphasis in original). If Plaintiffs' jaw problems were not, or could not have been, caused by a dental procedure, a dental screening seemingly would not have prevented their injury. NPC has raised the factual possibility that one or more of these Plaintiffs either may not have benefited from such a screening or actually ignored warnings to receive one. The Court will deny NPC's motion to exclude Dr. Marx's opinion on this basis, but without prejudice to its ability to raise those arguments in a non-*Daubert* pretrial motion *in*

[13] *See Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 437-38 (E.D.N.Y. 2011); *Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267, 276 (E.D.N.Y. 2012); *Jenkins v. Novartis Pharm. Corp.*, 2012 WL 6213494, at *4-5 (E.D. Ten. Dec. 13, 2012); *Guenther v. Novartis Pharm. Corp.*, 2013 WL 1277928 (M.D. Fla. Mar. 28, 2013); *Dopson-Troutt v. Novartis Pharm. Corp.*, 2013 WL 1339739 (M.D. Fla. Apr. 3, 2013); *Georges v. Novartis Pharm. Corp.*, 2012 WL 9064768, at *15 (C.D. Cal. Nov. 2, 2012); *Stambolian v. Novartis Pharm. Corp.*, 2013 WL 6345566, at *14 (C.D. Cal. Dec. 6, 2013); *Earp v. Novartis Pharm. Corp.*, 2013 WL 4854488 (E.D.N.C. Sept. 11, 2013); *Winter v. Novartis Pharm. Corp.*, 2012 WL 827305, at *7 (W.D. Mo. Mar. 8, 2012); *Hill v. Novartis Pharm. Corp.*, 2012 WL 5451816 (E.D. Cal. Nov. 7, 2012); *Mathews v. Novartis Pharm. Corp.*, 2013 WL 5780415, at 29 (S.D. Oh. Oct. 25, 2013).

limine. On this point, the record now before the Court is not so clear as to permit the conclusion that Dr. Marx's testimony is conclusively irrelevant.

B. Dr. Suzanne Parisian

Dr. Parisian is the founder of MD Assist, Inc., a regulatory and medical consulting firm specializing in matters regarding the FDA's regulation of products. ECF No. 77-13 at 2. She holds a medical degree and a Masters degree in biology and worked for many years for various regulatory agencies, including the FDA. *Id.* at 2-7. As a consultant, she provides information to individuals, manufacturers, and organizations with respect to various FDA requirements. *Id.* at 7. NPC seeks to exclude Dr. Parisian's opinions as to three issues: (1) NPC's compliance with FDA regulations; (2) the adequacy of the warnings NPC included in the Zometa labeling; and (3) regulatory causation.[14]

1. Regulatory Compliance

Where, as here, plaintiffs have asserted claims based on violations of FDA regulations, Zometa courts have routinely allowed Dr. Parisian to testify as to the general FDA regulatory scheme governing pharmaceutical drugs due to her significant experience with the FDA and its regulations regarding new drug application, approval, monitoring, and labeling.[15] However, some Zometa courts have expressly excluded her opinion on whether NPC's specific conduct

[14] The parties have agreed that Dr. Parisian will not testify about any of the following subjects: (1) the state of mind, intent, or motives of NPC or the FDA, or any current or former employees of either, (2) alleged "ghost writing" or NPC funding of publications on Zometa, (3) medical causation and diagnosis, (4) whether NPC acted reasonably based on industry standards, and (5) whether NPC failed to adequately monitor the Aredia/Zometa clinical trials. ECF No. 77 at 10 n.11.

[15] *See Lemons v. Novartis Pharm. Corp.*, 849 F. Supp. 2d 608, 614 (W.D.N.C. 2012); *Deutsch*, 768 F. Supp. 2d at 464-65; *Forman v. Novartis Pharm. Corp.*, 794 F. Supp. 2d 382, 384-85 (E.D.N.Y. 2011); *Davids*, 857 F. Supp. 2d at 276; *Dopson-Troutt v. Novartis Pharm. Corp.*, 2013 WL 1344755, at *4 (M.D. Fla. Apr. 2, 2013); *Taylor v. Novartis Pharm. Corp.*, 2013 WL 5118945, at *7 (S.D. Fla. Apr. 22, 2013); *Jenkins*, 2012 WL 6213494 at *6; *Stambolian*, 2013 WL 6345566 at *8; *Georges*, 2012 WL 9064768 at *10-11; *Brown v. Novartis Pharm. Corp.*, 2012 WL 9082901 (E.D.N.C. Sept. 20, 2012); *Hill v. Novartis Pharm. Corp.*, 2012 WL 5451809 (E.D. Cal. Nov. 7, 2012); *Guenther*, 2013 WL 1278089 at *2; *Earp*, 2013 WL 4854488 at *3; *Mathews*, 2013 WL 5780415 at *24.

concerning Zometa complied with FDA regulations as an improper legal conclusion.[16] These courts have drawn an appropriate boundary for purposes of Rule 702, and the Court concludes that Dr. Parisian may testify generally about the FDA's regulation of pharmaceutical drugs and how the regulatory scheme operates, but may not offer a conclusion as to whether NPC complied with FDA regulations in its actions regarding Zometa.

2. Adequacy of Warnings

With the exception of one case[17], Zometa courts have uniformly allowed Dr. Parisian to testify about the FDA's requirements for labeling and the adequacy of Zometa warnings and labels due to her experience and expertise with the FDA.[18] The Court finds this body of case law persuasive and concludes that Dr. Parisian's opinion on this issue is admissible with the exception of any testimony as to what prescribing oncology physicians would have done had they received different warnings for Zometa. Such testimony would require an impermissible degree of speculation from Dr. Parisian, as she is not an oncologist.[19]

3. "Regulatory Causation" Testimony

Pursuant to the consistent guidance of Zometa courts on this issue[20], Dr. Parisian will not be permitted to offer causation testimony of any kind, including "regulatory causation" or "causal association" opinions related to compliance with 21 C.F.R. § 201.57. Plaintiffs have

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[16] *See Lemons*, 849 F. Supp. 2d at 615; *Taylor*, 2013 WL 5118945 at *7; *Jenkins*, 2012 WL 6213494 at *6; *Stambolian*, 2013 WL 6345566 at *9; *Georges*, 2012 WL 9064768 at *9; *Earp*, 2013 WL 4854488 at *3; *Mathews*, 2013 WL 5780415 at *24.

[17] *Earp v. Novartis Pharm. Corp.*, 2013 WL 4854488 (E.D.N.C. Sept. 11, 2013).

[18] *See Lemons*, 849 F. Supp. 2d at 615; *Forman*, 794 F. Supp. 2d 382, *Davids*, 857 F. Supp. 2d at 276; *Chiles v. Novartis Pharm. Corp.*, 923 F. Supp. 2d 1330, 1333 (M.D. Fla. 2013); *Dopson-Troutt*, 2013 WL 1344755 at *4; *Taylor*, 2013 WL 5118945 at *8; *Jenkins*, 2012 WL 6213494 at *6; *Stambolian*, 2013 WL 6345566 at *10-11; *Georges*, 2012 WL 9064768 at *11; *Brown*, 2012 WL 9082913 at *7-9; *Hill*, 2012 WL 5451809 at *2; *Guenther*, 2013 WL 1278089 at *3; *Mathews*, 2013 WL 5780415 at *25; *Winter*, 2012 WL 827305 at *5.

[19] *See Stambolian*, 2013 WL 6345566 at *11; *Georges*, 2012 WL 9064768 at *11.

[20] *See Dopson-Troutt*, 2013 WL 1344755 at *3; *Taylor*, 2013 WL 5118945 at *8-9; *Stambolian*, 2013 WL 6345566 at *9; *Brown*, 2012 WL 9082913, at *7; *Guenther*, 2013 WL 1278089 at *2-3; *Mathews*, 2013 WL 5780415 at *24.

failed to sufficiently differentiate such testimony from general medical causation testimony, which Dr. Parisian is not qualified to give.

C. Professor Wayne Ray

Prof. Ray is a Professor of Preventive Medicine at Vanderbilt University School of Medicine, where he also serves as the Director of the Division of Pharmacoepidemiology and Master of the Public Health Program. ECF No. 79-7 at 2. He has extensive experience designing, conducting, and analyzing pharmacoepidemiologic studies. *Id.* at 2-3. For purposes of these cases, Prof. Ray performed a meta-analysis[21] examining the causal relationship between IV BPs and ONJ. ECF No. 79-7 at 17-30. NPC seeks to exclude his opinion testimony on a grand total of seven topics: (1) the relative risk of developing ONJ through IV BP use pursuant to Table 5 of his meta-analysis; (2) his Bradford Hill analysis[22] on causation; (3) the increased risk of ONJ in patients treated with Zometa rather than Aredia; (4) his causation opinion based on anecdotal case reports; (5) the biological plausibility of IV BPs increasing the risk of ONJ; (6) whether NPC could have reached a causation conclusion connecting IV BPs and ONJ as early as 2003; and (7) the incidence rate of ONJ in IV BP patients.

Joining several of its sister courts[23], this Court will allow Prof. Ray to testify as to all but two of those subjects. He may not opine on the increased risk of ONJ in patients treated with

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[21] A meta-analysis is "a technique used to combine the results of several studies to enhance the precision of the estimate of the effects, size, and reduce the plausibility that [an association] is due to random sampling error." *Deutsch*, 768 F. Supp. at 452 (citing Michael D. Green et al., *Reference Guide on Epidemiology*, in Reference Manual on Scientific Evidence 333, 335) (Fed.Jud.Ctr.2d ed.2000). "Performing a meta-analysis on cohort studies allows a researcher to determine the relative risk and the attributable risk to individuals of using a particular drug." *Id.*

[22] A Bradford Hill analysis is a method of establishing causation from epidemiologic data that requires review of nine criteria, including temporal relationship, replication of the findings, biological plausibility, consideration of alternative explanations, cessation of exposure, specificity of the association, and consistency with other knowledge. ECF No. 79-7 at 37-38.

[23] *See Deutsch*, 768 F.Supp.2d at 451-60; *Davids*, 857 F. Supp. 2d at 276; *Mathews*, 2013 WL 5780415 at *25-28; *Georges*, 2013 WL 5217198 at *15-16; *Winter*, 2012 WL 827305 at *9-15; *Jenkins*, 2013 WL 241783 at *2-5; *but*

Zometa as opposed to Aredia because Table 6 of his meta-analysis, which is the basis for that opinion, failed to account for duration of therapy when comparing the risks of Zometa and Aredia – a flaw identified by other Zometa courts.[24] Additionally, while Prof. Ray may give his opinion on the incidence rate of ONJ in IV BP patients, he may not subjectively characterize ONJ in such patients as "not rare."[25]

D. Dr. James Vogel

Dr. Vogel is a practicing oncologist and hematologist and an Associate Professor at the Mount Sinai School of Medicine, Division of Hematology/Medical Oncology. ECF No. 75-7 at 2. The MDL Court ruled that his testimony "concerning general causation and the scientific and medical accuracy of the warnings given by [NPC]" was admissible. ECF No. 75-2 at 4-5. NPC seeks to exclude Dr. Vogel's testimony on four issues: (1) whether pre-Zometa dental treatment measures reduce the risk of BRONJ; (2) the incidence rate of ONJ in IV BP patients; (3) the viability of alternative IV BP dosing durations and regimens; and (4) the biological mechanism by which IV BP drugs allegedly cause BRONJ.[26]

1. Pre-Zometa Dental Treatment Measures

Zometa courts have consistently found Dr. Vogel qualified to offer an opinion as to the effectiveness of pre-Zometa dental screenings in preventing BRONJ.[27] The Court will deny

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see Hogan, 2011 WL 1533467 at *7-8 (precluding Prof. Ray from testifying as to when NPC could have concluded that IV BPs caused ONJ).

[24] *See Deutsch*, 768 F.Supp.2d at 457-58; *Mathews*, 2013 WL 5780415 at *27; *Winter*, 2012 WL 827305 at *11; *Jenkins*, 2013 WL 241783 at *3-4.

[25] *See Deutsch*, 768 F.Supp.2d at 459; *Jenkins*, 2013 WL 241783 at *5; *Mathews*, 2013 WL 5780415 at *28; *Winter*, 2012 WL 827305 at *12; *Georges*, 2013 WL 5217198 at *16.

[26] Plaintiffs have stipulated that they do not intend to solicit "corporate conduct" testimony from Dr. Vogel. ECF No. 91 at 12. Therefore, NPC's motion as to that testimony will be denied as moot.

[27] *See Deutsch*, 768 F.Supp.2d at 438-40; *Davids*, 857 F. Supp. 2d at 276; *Georges*, 2013 WL 5217198 at *15; *Earp*, 2013 WL 4854488 at *4; *Mathews*, 2013 WL 5780415 at *22; *but see Jenkins*, 2013 WL 811766 at *2 (finding that

NPC's motion to exclude Dr. Vogel's opinion without prejudice, reserving its ability to revisit its arguments in a pretrial motion *in limine* for the same reasons it articulated with regard to Dr. Marx's opinion on the same subject (because NPC has raised the factual possibility that such testimony may be irrelevant to these cases).

2. ONJ Incidence Rate in IV BP Patients

The Court concurs with the uniform conclusions of other Zometa courts that have weighed the admissibility of Dr. Vogel's opinion on the rate of ONJ incidence in IV BP patients.[28] Because NPC's objections to this opinion go to its weight and not its admissibility, the Court will allow Dr. Vogel to testify on this subject.

3. Alternative Dosing Durations and Regimens

Plaintiffs seek to have Dr. Vogel testify that a reduced dosing schedule of Zometa is equally effective and presents less risk of BRONJ and that NPC failed to release information about possible alternative dosing schedules. NPC argues that Dr. Vogel's opinion is not sufficiently reliable because his suggested alternative Zometa regimen has not been approved by the FDA and was rejected as unreliable and medically inadvisable by the American Society of Clinical Oncology, and because he relies upon a single study and an article in support of his theory.[29] NPC also contends that this testimony is irrelevant, because the study Dr. Vogel relies upon was not published until after Mr. Orr and Ms. Rowland stopped taking Zometa and after

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the parties' agreement that Dr. Vogel would not testify as to pretreatment dental screenings as an ONJ prevention measure to be "well-supported").

[28] *See Deutsch*, 768 F.Supp.2d at 441; *Davids*, 857 F. Supp. 2d at 276; *Georges*, 2013 WL 5217198 at *15; *Taylor*, 2013 WL 5118945 at *4; *Earp*, 2013 WL 4854488 at *4; *Mathews*, 2013 WL 5780415 at *22-23.

[29] NPC points to the rulings in *Brodie v. Novartis Pharm. Corp.*, No. 4:10CV0138-HEA, at 3 (E.D. Mo. Jan. 20, 2012) (finding that "Dr. Vogel's opinions that NPC should have disseminated information on alternate dosing and duration of treatment are not within his expertise, nor are they based on scientifically reliable sources; therefore, he will not be allowed to opine on such."), and *Conklin v. Novartis Pharm. Corp.*, 2012 WL 4127295, at *9-10 (E.D. Tex. Sept. 18, 2012) (prohibiting a similar opinion from Dr. Marx) for support.

Mr. Machen began taking Zometa.[30] However, in nearly identical circumstances, the court in *Taylor v. Novartis Pharm. Corp.*, 2013 WL 5118945, at *5 (S.D. Fla. Apr. 22, 2013), found that Dr. Vogel had a sufficient factual basis (the same study) to present his qualified interpretation of its results to the jury. Additionally, in *Deutsch v. Novartis Pharm. Corp.*, 768 F.Supp.2d 420, 444-45 (E.D.N.Y. 2011), the court held that "Dr. Vogel has been established as an expert who is qualified to opine on the dose-response relationship generally and his extensive discussion of the studies supporting and questioning that relationship support the reliability of his opinions." The Court concludes that Dr. Vogel is qualified to offer an expert opinion on this issue, but to the extent that NPC has raised a non-*Daubert* question of traditional relevance to the claims at hand, the Court will deny NPC's motion based on that argument without prejudice to its later reassertion in a pretrial motion *in limine*.

4. Biological Mechanism Opinion

Pursuant to the well-reasoned opinions of other Zometa courts, which have found Dr. Vogel qualified by experience to testify as to the biological mechanism by which IV BPs affect jaw bones[31], the Court will allow him to offer an opinion on that subject.

E. Dr. Keith Skubitz

Dr. Skubitz is a Professor of Medicine at the University of Minnesota Medical School, where he conducts research on basic biologic aspects of cancer and clinical cancer therapy and regularly sees patients in the oncology clinic. ECF No. 81-3 at 2. The MDL Court found him

[30] In *Mathews v. Novartis Pharm. Corp.*, 2013 WL 5780415 at *23, the court held that Dr. Vogel's opinion on this issue was not relevant and therefore inadmissible because NPC asserted that Plaintiffs had ceased their IV BP drug therapy before the proffered study concerning reduced dosing was published, and Plaintiffs failed to respond to NPC's argument.

[31] *See Deutsch*, 768 F.Supp.2d at 438; *Davids*, 857 F.Supp.2d at 276; *Georges*, 2013 WL 5217198 at *15; *Taylor*, 2013 WL 5118945 at *6; *Mathews*, 2013 WL 5780415 at *23. The Court is aware of only one federal district court that has, without providing its reasoning, precluded Dr. Vogel from testifying about his understanding of the biological mechanism by which IV BPs may cause ONJ. *See Earp*, 2013 WL 4854488 at*4.

qualified to testify as to general causation and adequacy of warnings. ECF No. 81-2. NPC seeks to prevent Dr. Skubitz from testifying as an expert on (1) the viability of alternative IV BP dosing durations and regimens; (2) whether pre-Zometa dental treatment measures reduce the risk of BRONJ; and (3) the incidence rate of ONJ in IV BP patients.

Other Zometa courts have found Dr. Skubitz to be qualified to testify to the ONJ incidence rate in Zometa patients[32], and for the same reasons discussed with respect to Dr. Vogel's opinion on the same topic, the Court will allow Dr. Skubitz to offer his opinion at trial. As for Dr. Skubitz's other opinions, the Court has already discussed the relevance concerns related to those subjects raised by NPC and on that basis will deny NPC's motion as to those issues without prejudice to their later reassertion in a pretrial motion *in limine*.[33]

F. Case-Specific Experts

1. Non-Retained Treating Physicians

NPC also pursues exclusion of the testimony of each of Plaintiffs' treating physicians that Plaintiffs have offered as expert witnesses on the topic of specific causation. Ms. Rowland has designated Dr. Marc Samuels ("Dr. Samuels"), her dentist, and Dr. William Chung ("Dr. Chung"), her oral surgeon, as such witnesses. However, Ms. Rowland has not presented any evidence that either physician is qualified to opine on the causation of ONJ. At his deposition, Dr. Samuels testified that he had no opinion as to whether Zometa causes ONJ. ECF No. 70-1 at 47-48. Dr. Chung stated at his deposition that he did not consider himself an expert in BRONJ. ECF No. 70-2 at 16.

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[32] *See Deutsch*, 768 F.Supp.2d at 441; *Davids*, 857 F.Supp.2d at 276; *Mathews*, 2013 WL 5780415 at *22-23.

[33] At a Telephonic Status Conference held on January 16th, 2014, counsel for Plaintiffs advised the Court that they did not plan to call Dr. Skubitz to testify at trial unless Dr. Vogel's testimony was excluded. *See* ECF No. 117. Because the Court has ruled Dr. Vogel's testimony is admissible on each issue as to which Dr. Skubitz is also offered, NPC's motion to exclude Dr. Skubitz's testimony may well be moot at this point. The Court offers this narrative as another reason it considers its denial without prejudice as to the two issues Plaintiffs seek to have both witnesses testify on as the appropriate course of action.

Mr. Machen designates Dr. Derek Kelly ("Dr. Kelly"), his oral surgeon, and Dr. Mark Stein ("Dr. Stein"), his dentist, as experts testifying on the issue of causation. Much like Ms. Rowland, Mr. Machen has presented no concrete qualifications for either physician to present such testimony. Dr. Stein testified at his deposition that he does not consider himself an expert on ONJ, ECF No. 96-1 at 7, and that he had no opinion as to whether Mr. Machen had ONJ. ECF No. 71-1 at 44. At his deposition, Dr. Kelly also testified that he did not consider himself an expert on ONJ or its causes and stated that he had "no intentions" of offering an opinion as an expert in this case. ECF No. 71-3 at 11-13.

Mrs. Orr offers Dr. Joseph Cillo ("Dr. Cillo"), Mr. Orr's oral surgeon, and Dr. David Roodman ("Dr. Roodman"), his oncologist, as expert witnesses on causation. Both physicians at least believe themselves to be experts on ONJ and appear to have some expertise to support that assertion. ECF No. 90-2 at 172-73, 206. Dr. Cillo completed a fellowship with Dr. Marx where he treated and managed patients with BRONJ. He has treated in total at least 50 patients suffering from BRONJ and has lectured on and written a peer-reviewed article on BRONJ. *Id.* at 69-76. Dr. Roodman has lectured on BRONJ and co-authored the American Society of Clinical Oncology guidelines for use of bisphosphonates in multiple myeloma patients. *Id.* at 231-88. However, Dr. Cillo was never deposed in this case, and Dr. Roodman never unequivocally testified at deposition that he believed to a reasonable degree of medical certainty that Mr. Orr's condition was caused by his Zometa use. *Id.* at 192.

In the Third Circuit, treating physicians' opinions on prognosis and causation are inherently expert testimony. *Pease v. Lycoming Engines*, 2012 WL 162551, at *12 (E.D. Pa. Jan. 19, 2012). However, when a treating physician's causation conclusion is excluded as unreliable, he may still be permitted to testify about his examination of the plaintiff, the tests he

conducted, and any diagnosis he reached. *Heller v. Shaw Indus.*, 167 F.3d 146, 159 n.8 (3d Cir. 1999) (citation omitted). Plaintiffs' treating physicians are therefore free to testify as to personal knowledge they gained from their examinations of Plaintiffs – statements made to them by Plaintiffs during care and treatment, their own examinations, diagnoses, and course of treatment, and Plaintiffs' prognoses based on their observations during treatment. *Damiani v. Momme*, 2012 WL 1657920, at *4 (E.D. Pa. May 11, 2012). "What these treating physicians may not do is offer independent opinions as to the cause of [p]laintiff's injuries." *Id.*

The Court will not allow the treating physicians for Ms. Rowland or Mr. Machen to testify as to causation in any respect given their deposition testimony. They may, however, testify about their care and treatment of Plaintiffs based on their personal knowledge and examinations. The Court will allow Mr. Orr's treating physicians to opine on causation due to their experience with BRONJ, but only to the extent that they formed any such opinion from their treatment of Mr. Orr and not at the request of counsel.[34] *See Pease*, 2012 WL 162551, at *13 n.23.

2. Retained Experts

a. The *Rowland* and *Machen* Cases – Dr. Talib Najjar

Dr. Najjar is a board certified oral pathologist and oral and maxillofacial surgeon. ECF No. 70-3 at 15-30. He is a specialist in jaw disease, has treated patients with BRONJ, and has researched ONJ in rats. *Id.* Two other Zometa courts have allowed Dr. Najjar to give expert testimony on the topic of causation.[35] Dr. Najjar concludes in his expert reports to a reasonable

[34] The Court notes that Mrs. Orr also originally designated Dr. William Hall, Mr. Orr's oral surgeon, as an expert witness on causation but has since withdrawn that designation. ECF No. 90-1 at 2. Plaintiff reserved the right to call Dr. Hall to testify about his care and treatment of Mr. Orr and any related diagnosis he made, *id.*, and the Court will allow such testimony to the extent that it is consistent with this Opinion.

[35] *See Bowles v. Novartis Pharm. Corp.*, 2013 WL 5297257 (S.D. Oh. Sept. 19, 2013); *Sheffer v. Novartis Pharm. Corp.*, 2013 WL 5276558 (S.D. Oh. Sept. 18, 2013).

degree of medical certainty, based on differential diagnoses[36] he conducted, that Ms. Rowland and Mr. Machen both developed BRONJ as a result of their Zometa treatment. ECF No. 70-3 at 2-4; ECF No. 71-4 at 2-3. NPC seeks to exclude his testimony to that effect.

As to Ms. Rowland, the Court concludes that Dr. Najjar may testify regarding causation of her ONJ. NPC's main objections to Dr. Najjar's testimony are that he did not rule out osteomyelitis as a possible cause in his differential diagnosis and that he only reviewed Ms. Rowland's medical records in making his determination. A medical expert's causation conclusion should not be excluded because he failed to rule out every possible alternative cause of injury or illness. *Heller*, 167 F.3d at 156. Only "where a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause" is that doctor's methodology unreliable. *Paoli*, 35 F.3d at 759 n.27 (emphasis in original). Dr. Najjar considered osteomyelitis and a number of other possible causes in his expert report and concluded that they were not probable or were secondary causes to BRONJ. ECF No. 70-3 at 3. Once a defendant's suggested alternative causes are adequately addressed by the expert, they go to the weight of his testimony, not its admissibility. *Kannankeril*, 128 F.3d at 808. Additionally, evaluation of a plaintiff's medical records is a reliable method even in the absence of a physical examination. *Paoli*, 35 F.3d at 762. Therefore, Dr. Najjar's causation opinion as to Ms. Rowland is admissible for Rule 702 purposes, and NPC's objections may properly be addressed with cross-examination.

NPC raises different issues with respect to Dr. Najjar's causation opinion on Mr. Machen. NPC argues that since Dr. Najjar found no necrotic or exposed jawbone during his examination

[36] A differential diagnosis is the "basic method of internal medicine" and involves assessing causation with respect to a particular individual. *Paoli*, 35 F.3d at 755, 57. Pursuant to a valid differential diagnosis, a physician tests a falsifiable hypothesis in an attempt to rule out alternative causes using a reliable but not necessarily generally accepted methodology. *Id.*

of Mr. Machen, he could not credibly diagnose him with osteo*necrosis* of the jaw (literally, dead jawbone). The American Association of Oral and Maxillofacial Surgeons ("AAOMS") criteria for diagnosing Stage I BRONJ requires that the patient have exposed bone or exposed necrotic bone for a period of 6-8 weeks. ECF No. 71-6 at 4. Dr. Najjar admitted during his deposition that Mr. Machen's symptoms did not meet those recognized diagnostic BRONJ criteria, ECF No. 71-5 at 12, but testified that he believed Mr. Machen suffered from a "BRONJ-like lesion," ECF No. 92-2 at 176, or bony defect in his jaw that was in fact Stage I BRONJ pursuant to his own criteria. *Id.* at 143. Plaintiff argues that this diagnosis is akin to "Stage 0" BRONJ, which the AAOMS defined in a 2009 position paper as found in "patients with no clinical evidence of necrotic bone, but present with non-specific symptoms or clinical and radiographic findings." *Id.* at 82.

The Court concludes that Dr. Najjar may testify to the causation of Mr. Machen's ONJ. Dr. Najjar is eminently qualified by experience as an expert in ONJ and BRONJ and used a differential diagnosis to come to his causation conclusion. He utilized reliable scientific methods, including a physical examination of Mr. Machen, review of his medical records, and consideration and subsequent elimination of alternative causes. *See Heller*, 167 F.3d at 156; ECF No. 92-2 at 379-385. The fact that a physician used a differential diagnosis "to 'testify to a novel conclusion' is not sufficient grounds for excluding his testimony." *Heller*, 167 F.3d at 156 (quoting *Paoli*, 35 F.3d at 759 n.27).

The court in *Bessemer v. Novartis Pharm Corp.*, No. MID-L-1835-08, slip op. at 6-7, 11 (N.J. Super. Ct. Law Div. Apr. 30, 2010), confronted a similar *Daubert* challenge. NPC sought to exclude the case-specific causation testimony of one of the plaintiff's experts on the grounds that the plaintiff had no history of exposed bone and therefore, under the AAOMS criteria, could

not reliably be diagnosed with BRONJ. *Id.* at 7. The expert diagnosed the plaintiff with Stage 0 BRONJ, which NPC alleged is "not meant to assess a causal relationship between bisphosphonates and ONJ but rather serves as a treatment guideline." *Id.* The Court disagreed with NPC, writing:

> [The plaintiff] need not demonstrate that she had exposed bone to prove she suffered an injury from bisphosphonate use. Likewise, [the expert's] opinion need not be limited to the AAOMS guidelines. The admissibility of [the expert's] opinion depends on whether he used data generally relied upon by experts in the field in reaching his conclusion and whether his methodology was proper.

Id. The Court concurs with the *Bessemer* court's conclusion and finds it to be consistent with Third Circuit guidance – the crux of the admissibility question is reliable methodology, not the acceptability of the conclusion itself. *See Paoli*, 35 F.3d at 744. Because Dr. Najjar is qualified to testify as to ONJ causation and used reliable methodology to come to his conclusion about what caused Mr. Machen's injuries, his expert causation opinion is admissible under Rule 702.

b. The *Orr* Case – Dr. Daniel Atallah

Dr. Atallah is Director of Oral and Maxillofacial Surgery at Miami VA Medical Center and Assistant Professor of Clinical Surgery in the Division of Oral and Maxillofacial Surgery at Miami University Miller School of Medicine. ECF No. 69-1 at 22. He has experience regularly evaluating and treating patients with BRONJ and was a resident under Dr. Marx at the time BRONJ cases first became frequent. *Id.* His expert report concludes to a reasonable degree of medical certainty that Mr. Orr developed BRONJ as a result of his Zometa treatment. NPC seeks to exclude his causation testimony primarily on the basis that the differential diagnosis Dr. Atallah conducted with respect to Mr. Orr did not properly rule out several alternative causes documented in Mr. Orr's medical records, including chemotherapy, corticosteroid use, and osteomyelitis.

The Court concludes that Dr. Atallah may testify on the issue of the causation. He is qualified as an expert through his experience treating BRONJ patients, and it is axiomatic that when conducting a differential diagnosis, a physician cannot and need not eliminate all possible causes of the patient's injury for his causation opinion to become admissible; he merely must rule out obvious alternative causes. *Heller*, 167 F.3d at 156. Dr. Atallah considered a number of other possible explanations for Mr. Orr's injury and specifically ruled out numerous alternative causes including cancer, chemotherapy, corticosteroid use, radiation, and osteomyelitis for reasons that he explained in his expert report and further at his deposition. ECF No. 69-1 at 22-27; ECF No. 90-2 at 21-67. The Court therefore will allow him to testify as an expert witness on case-specific causation, as NPC may properly address its objections to his testimony on cross-examination.

G. Mrs. Orr's Motion to Exclude Certain Testimony of NPC's Case-Specific Experts

1. Dr. Peter Pickens

Dr. Pickens is a Clinical Professor of Medicine at the Temple University School of Medicine. *Orr v. Novartis Pharm. Corp.*, MDL No. 3:06-MD-1760, 3:07-cv-00472, ECF No. 37-2 at 2 (M.D. Ten. filed July 16, 2012). He has extensive experience with metastatic bone cancer, including multiple myeloma. *Id.* Mrs. Orr seeks to exclude Dr. Pickens from testifying that he found the information about ONJ provided in the Zometa labels and warnings adequate to perform a proper risk/benefit analysis prior to prescription, arguing that he is not qualified to offer such an opinion.

As an oncologist, Dr. Pickens has had many multiple myeloma patients and often prescribes medications to such patients. Under Pennsylvania law, prescribing physicians have a

duty to be fully aware of the characteristics of the drug they are prescribing and to advise patients of any dangers or side effects associated with use of the drug. *Coyle by Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991) (quoting *Makripodis by Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987)). As a result, the warnings that accompany prescription drugs are directed to the physician, who then uses his independent medical judgment, data supplied by the manufacturer, medical literature, and other sources to decide whether to prescribe the drug to a particular patient. *Id.* Dr. Pickens has examined the Zometa labels and warnings and may testify as to their adequacy in the context of his own experience as a prescribing oncologist. *See Deutsch*, 768 F.Supp.2d at 440 (excluding opinions from Drs. Vogel and Skubitz that Zometa labels and warnings were inadequate because they failed to comply with FDA regulations, but allowing them to testify as to the adequacy of the labels from the perspective of oncologists and prescribing physicians).

2. Dr. Anthony Mega

Dr. Mega is an Associate Professor of Medicine at the Warren Alpert School of Medicine at Brown University in the Division of Hematology/Oncology. *Orr*, MDL No. 3:06-MD-1760, 3:07-cv-00472, ECF No. 37-3 at 2 (M.D. Ten. filed July 16, 2012). He has over a decade of experience prescribing and using Zometa and estimates that 30 patients in his practice receive monthly injections of either Aredia or Zometa. *Id.* Over eleven years, Dr. Mega has personally treated four patients who developed ONJ while using IV BPs. *Id.* Mrs. Orr seeks to exclude his expert testimony related to (1) general causation of ONJ, (2) Mr. Orr's dental condition, and (3) the adequacy of the Zometa warnings and labels, on the basis that he is not qualified to give such testimony.

For the same reasons the Court allowed Dr. Perkins to opine on the adequacy of the Zometa warnings and labels, the Court will allow Dr. Mega's testimony as to that issue from the perspective of a prescribing oncologist. Dr. Mega primarily bases his general ONJ causation opinion on his review of the relevant medical literature and his handful of personal experiences as a treating physician. *Id.* at 6-7. The Third Circuit has articulated a liberal policy of admissibility under Rule 702 – an expert may be qualified by a broad range of knowledge, skills, and training. *Paoli*, 35 F.3d at 741. Dr. Mega meets that standard by virtue of his standing as an oncologist who has prescribed Zometa numerous times and treated several ONJ patients. The fact that a doctor is not a specialist in a particular field goes to the weight of his testimony, not its admissibility. *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 855-56 (3d Cir. 1990). Plaintiff may therefore adequately address Dr. Mega's alleged deficiencies in specialized ONJ expertise on cross-examination.

Mrs. Orr also claims that Dr. Mega will testify about her late husband's dental condition and identify it as osteomyelitis[37] but is unqualified to do so. The Court first notes that the parties have provided precious little in the way of evidence or argument to show that Dr. Mega is or is not qualified to testify about osteomyelitis or dental conditions generally. Mrs. Orr's entire argument for exclusion of this vaguely defined opinion is that "there is no evidence in this case that [Dr. Mega] has any expertise in any field of dentistry." 2:12-cv-01715-MRH, ECF No. 8-13 at 5. NPC's similarly laconic position is that "[Dr. Mega] is an oncologist whose experience includes evaluating the developing medical literature and making risk/utility decisions (including as relates to oral complications specifically) in prescribing medications (including Zometa) for

[37] Osteomyelitis is an inflammation of the bone marrow and adjacent bone. Stedman's Medical Dictionary 1391 (28th ed. 2006).

patients. He certainly is qualified to opine regarding...other dental conditions." *Id.*, ECF No. 8-23 at 14.

In any event, despite the Third Circuit's liberal policy of admissibility, the Court can imagine no reason why Dr. Mega, an oncologist, should be permitted to testify about Mr. Orr's general dental condition or about osteomyelitis. The disputed portion of Dr. Mega's report states, "Mr. Orr was significantly immunocompromised. As a result he developed osteomyelitis of the jaw, which responded favorably to the prescribed antibiotic therapy." *Orr*, MDL No. 3:06-MD-1760, 3:07-cv-00472, ECF No. 37-3 at 9. The record reflects that Dr. Nalini Rao, an infectious disease specialist, diagnosed Mr. Orr with "acute and chronic osteomyelitis." 2:12-cv-01715-MRH, ECF No. 8-25 at 44. NPC may choose to offer Dr. Rao as an expert to testify about his diagnosis, but it cannot transmogrify Dr. Mega's testimony into an admissible expert opinion on Mr. Orr's dental condition by offering the diagnosis or other medical opinions of Dr. Rao or any other physician through Dr. Mega. *See Hartle v. FirstEnergy Generation Corp.*, 2014 WL 1235826, at *6 (W.D. Pa. Mar. 25, 2014) (while an expert may rely on other experts, he may not be the mouthpiece of the medical opinions of an expert in a different specialty). The Court will accordingly grant Mrs. Orr's motion to exclude any expert testimony from Dr. Mega on the subject of Mr. Orr's dental condition.

IV. CONCLUSION

For the reasons stated in this Opinion, the Court will:

(1) Grant in part and deny in part Defendant's Motion to Exclude Causation Testimony of Plaintffs' Case-Specific Retained and Non-Retained Experts in the *Orr* Case (ECF No. 69);

(2) Grant in part and deny in part Defendant's Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses in the *Orr* Case (2:12-cv-01715-MRH, ECF No. 8-14, originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 26);

(3) Grant in part and deny in part Defendant's Motion to Exclude Causation Testimony of Plaintffs' Case-Specific Retained and Non-Retained Experts in the *Rowland* Case (ECF No. 70);

(4) Grant in part and deny in part Defendant's Motion to Exclude Causation Testimony of Plaintffs' Case-Specific Retained and Non-Retained Experts in the *Machen* Case (ECF No. 71);

(5) Deny Defendant's Motion to Exclude Testimony of Dr. Robert Marx (ECF No. 72);

(6) Deny Defendant's Motion to Exclude Testimony of Dr. James Vogel (ECF No. 74);

(7) Grant in part and deny in part Defendant's Motion to Exclude Testimony of Dr. Suzanne Parisian (ECF No. 76);

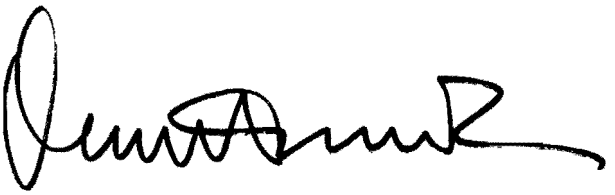
(8) Grant in part and deny in part Defendant's Motion to Exclude Testimony of Prof. Wayne Ray (ECF No. 78);

(9) Deny Defendant's Motion to Exclude Testimony of Dr. Keith Skubitz (ECF No. 80);

(10) Grant in part and deny in part Defendant's Motion to Exclude Testimony of Plaintiff's Experts Dr. Suzanne Parisian, Dr. Robert Marx, Dr. Robert Fletcher, Prof. Wayne Ray, Dr. Keith Skubitz, and Dr. James Vogel (2:12-cv-01715-MRH, ECF No. 8-16, originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 28); and

(11) Grant in part and deny in part Plaintiff Orr's Motion to Exclude Certain Testimony of Defendant's Case-Specific Experts, 2:12-cv-01715-MRH, ECF No. 8-12 (originally filed in M.D. Ten., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, at ECF No. 20).

An appropriate Order will follow.



Mark R. Hornak
United States District Judge

cc: All counsel of record
Dated: March 31st, 2014